Fresh Vegetables, Inc.
Post Office Box 1759 • Salinas, CA 93902 • Phone (831) 422-8871

April 3, 2003

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane Room 1061
HFA-305
Rockville, MD 20852

RE: Docket No. 02N-0278 RIN 0910-AC41, Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (68 FR 5428, February 3, 2003) Submission of Comments- Reg.

Dear Sir/Madam:

Thank you very much for the opportunity to provide comments and feedback on the above referenced proposed rule.

The proposed rule on "Prior Notice of Imported Food" is burdensome and goes beyond the Congressional mandate and that required to meet the security objectives stated in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. The proposed rule will have adverse implications on business operations and impede food product movement into the U.S particularly that of perishable commodities such as fresh fruits and vegetables which are harvested and imported into the U.S. for "just in time" inventory management and sale. The FDA has grossly underestimated the economic burden imposed by the proposed rules and the potential for trade disruption.

The Congressional mandate requires FDA to promulgate regulations for the purpose of enabling food articles to be inspected at the port of entry. However, the FDA under the proposed rule intends to collect additional information beyond what is required to facilitate inspection of food at the ports of entry. FDA proposes to use the additional information to facilitate product tracking to help in determining the source and cause of food safety and food security problems.

The FDA's definition of food to include "substances that migrate into food from packaging materials" unnecessarily expands the scope of the proposed rule.

The proposed rule is inconsistent with the U.S. international obligations under the World Trade Organization (WTO), North American Free Trade Agreement (NAFTA) and under the agreement on Technical Barriers to Trade (TBT). The information required under the proposed rule is unnecessarily burdensome and often times duplicative of the information supplied to Customs for importation of food products.

02N-0278 C156

The time required for notice (noon the preceding day), far exceeds the minimum 8 hours recommended by Congress and poses an additional burden on trade and commerce of perishable commodities such as fresh fruits and vegetables that are imported for "just in time" inventory and sale. Information on products to be shipped or availability of carriers (rail, truck or air cargo carriers) may not always be available 36 hours in advance of a shipment. These are impractical and difficult requirements and cannot be met under the current business environment, without significantly impeding the capability of a firm to import products into the U.S.

Under the proposed rule, FDA allows one amendment related to product identity two hours in advance of entry. However, importing fresh fruits and vegetables from bordering countries such as Mexico will require amendments for 100 percent of the submissions made. Amendments should be permitted for all product identity fields, growers, customs and carrier data. Importers should be permitted to amend multiple factors in a single amendment submission within one-hour of entry. The exact time when a shipment of product will cross the border into the U.S. will depend on Customs inspections to be completed once the trucks arrive at the port of entry. At peak hours, it is not unusual for trucks to wait at the border for a considerable amount of time for the Customs inspection to be completed.

The FDA should eliminate all unnecessary data elements from the prior notification and should make the notification as simple as possible while accomplishing the inspection of food at the port of entry.

The proposed rule requires most of the information already submitted by importers to the U.S. Customs to be provided in a different format to the FDA. The information provided to the U.S. Customs is adequate in enabling the FDA to arrange for inspection of imported foods and as such FDA should work with the Customs rather than promulgate new regulations to meet the intent of the Bioterrorism Act.

The proposed rule indicates that a product will be refused admission when the prior notice of entry submission is inadequate or incomplete. It is unclear if this will apply to entries that are voluntary or only for information that is mandatory. The FDA should provide clear guidance to industry and field personnel about the process and procedure for implementation of this regulation including an appeal mechanism in the event food products are held without adequate or appropriate cause. In the case of perishable food commodities such as fresh fruits and vegetables the quality and value of the products will be negatively impacted during storage. The FDA must explore avenues for expedited review of shipments of fresh fruits and vegetables that are held so the loss of value and quality can be minimized.

FDA must utilize the existing Customs Trade Partnership Against Terrorism (CTPAT) that sorts high-risk cargo from low risk cargo and creates a channel to facilitate importing products by firms with appropriate security systems.

The FDA has vastly underestimated the economic impact and the disruption of trade and commerce of this proposal. Under the proposed rule firms importing products into the U.S. will be required to file thousands of notices each year. Even a single shipping container with a variety of products, will under the proposed rule require numerous prior notices. The potential for any errors in making these submissions will result in delay of entry of products or to be held at the port thereby causing significant disruption in trade and commerce. This will require significant operational changes and evaluation of the information by multiple people requiring considerable amount of training and expense to comply with the new requirement.

The FDA must eliminate all duplicative and unnecessary data elements and must work closely with the Customs to perform inspections of food at the ports of entry.

Thank you for the opportunity to provide comments on this important subject.

Sincerely,

Mahipal Kunduru, Ph.D.,
Director Food Safety
Dole Fresh Vegetables Inc.,